

## **Best Practices and Compliance with USP 795 for Nonsterile Compounding eLearning Curriculum: Learning and Performance Objectives 11 eLessons with 11 hours of CE**

### **Introduction to Nonsterile Pharmacy Compounding (1 hour)**

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- List elements pertaining to nonsterile pharmacy compounding.
- Explain the fundamental principles of USP 795.
- Describe the industry standards for USP 795.
- Define the basic terms that apply to nonsterile pharmacy compounding.
- Recall basic terminology related to nonsterile pharmacy compounding.

### **Mathematics Review and Pharmaceutical Excipients (1 hour)**

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- Identify the correct formulas required to complete nonsterile pharmaceutical calculations.
- Correctly solve mathematical calculations/equations that relate to nonsterile compounding.
- Discuss pharmaceutical excipients used in nonsterile compounding.

### **Responsibilities of the Compounder and Compounding Facility Requirements (1 hour)**

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- Identify the responsibilities of the compounder and the designated person in USP 795.
- List the personnel qualifications identified by USP 795.
- Explain good hand hygiene, appropriate garbing, and use of PPE.
- Describe USP 795 requirements for nonsterile compounding facilities.
- Properly list requirements for a clean compounding environment.
- Explain basic ergonomics and how they apply to nonsterile compounding facilities and compounders.
- Discuss requirements, resources, and guidelines for preparing hazardous compounded nonsterile preparations (CNSPs).

### **Component Selection, Receipt, Handling, and Storage (1 hour)**

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- Define the requirements for component selection in USP 795.
- Describe the storage requirements per USP 795.
- Outline proper component-handling activities.
- Demonstrate the ability to read and understand a certificate of analysis (COA).
- Describe the requirements for receipt of component(s) in USP 795.



### **Nonsterile Compounding Equipment (1 hour)**

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- Define the requirements for the use of compounding equipment and USP 795.
- List the types of equipment and their basic functions used in nonsterile compounding.
- Evaluate the cleaning schedule for nonsterile compounding equipment.

### **Nonsterile Compounding Process (1 hour)**

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- Identify the different methods used to compound nonsterile preparations.
- Outline proper compounding techniques for each nonsterile dosage form.

### **Beyond-Use Dating (BUD) and Chemical Stability of Nonsterile Compounds (1 hour)**

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- Define basic terminology associated with beyond-use dates.
- Review USP Chapter 1112 and how it affects BUDs for CNSPs.
- Define stability considerations.
- Assign BUDs to nonsterile pharmaceutical compounds consistent with USP 795.

### **Packaging and Documentation of Nonsterile Formulations (1 hour)**

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- List the requirements for packaging and drug preparation containers.
- Describe the labeling process and requirements.
- Identify the elements required for proper development of master formulation records and compounding records.
- Identify methods to implement meaningful use of safety data sheets (SDS).
- Describe comprehensive, detailed standard operating procedures (SOPs) for nonsterile compounding practice.
- Review the transportation guidelines of compounded nonsterile preparations (CNSPs) in USP 795.

### **Quality Control and Release Testing in a Nonsterile Compounding Practice (1 hour)**

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- List the methods for release inspection required in USP 795.
- Describe different quality systems in USP 795.
- Explain how to handle product complaints and adverse event reporting.
- Define best practices for patient counseling of CNSPs.

### **Staff Training and Competency for Nonsterile Compounding (1 hour)**

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- Describe required staff training for personnel performing nonsterile compounding with USP 795.
- Identify qualities of a program that ensures effective initial and ongoing training.
- Review basic requirements for the training documentation in USP 795.
- Describe procedural training and evaluation documents with USP 795.



## Nonsterile Compounding eLearning Curriculum

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### Nonsterile Compounding for Animals (1 hour)

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- Define the requirements for animal compounding in USP 795.
- Discuss the laws, regulatory requirements, and conundrums associated with compounding for animals.
- Review responsibilities of the veterinarian.

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